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IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

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TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender neutral
fictitious names, and ABC
CORPORATION 1 through 10 (fictitious
names).
Defendants.

CIVIL ACTION No. 2:21-cv-10312-SJM-RSW

**PLAINTIFF/COUNTER-DEFENDANT TRUTEK CORP.'S REPLY TO
DEFENDANT-COUNTER PLAINTIFF BLUEWILLOW BIOLOGICS, INC.'S
OPPOSITION TO PLAINTIFF'S MOTION TO
DISMISS DEFENDANT'S COUNTERCLAIMS**

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BlueWillow did not adequately plead its first counterclaim demanding a declaratory judgment of non-infringement according to the requirements of *Twombly* and *Iqbal*.

2

BlueWillow did not adequately plead its second counterclaim demanding a declaratory judgment of patent invalidity according to the requirements of *Twombly* and *Iqbal*.

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Exhibits

1 Form 16 from Fed. R. Civ. P. (2004)

2 Comparison Between '802 Patent's Claims and BlueWillow's Non-Infringement Allegation

3 Pages From BlueWillow's Website (<https://www.bluewillow.com>)

1 On June 4, 2021, Plaintiff, Trutek Corp. ("Trutek") filed a Fed. R. Civ. P. 12(b)(6)
2 Motion to Dismiss the counterclaims of Defendant, BlueWillow Biologics, Inc.
3 ("BlueWillow") that were presented in BlueWillow's Answer to the Complaint. On June
4 25, 2021, BlueWillow presented a Brief in Opposition to Trutek's Motion. (Document
5 ECF 12 is hereinafter referred to as the "Opposition.") This present brief sets forth
6 Trutek's Reply to BlueWillow's Opposition.

7 ARGUMENT

8 BlueWillow began its Opposition brief by asserting that, "[t]his is a classic
9 nuisance patent lawsuit." This statement implies that actions of a patent owner to enforce
10 its patents against infringement are trivial unless the infringer is a large entity or unless
11 there is a high volume of sales of an infringing product. However, if a patent owner does
12 not enforce its patents, regardless of the size of the infringer or the amount of its sales, the
13 patent owner places its protected work in danger. The primary consequence of not
14 enforcing a patent is loss of its exclusive rights. In the Instant Lawsuit, Trutek seeks to
15 enforce its patent against a defendant that is not only making and selling an infringing
16 product but also is developing other products employing Trutek's patented technology.
17 While BlueWillow may view Trutek's efforts to enforce its '802 Patent as a private
18 nuisance, Trutek's decision to protect its intellectual property rights is not a trivial matter.

19 By naming Trutek as a Counter-Defendant and asserting its counterclaims,
20 BlueWillow presented a counter-complaint. In the interests of fair play and substantial
21 justice, this Court should evaluate a counter-complaint using the same standards as it
22 applies to an original complaint.

23 Fed. R. Civ. P. 8 sets forth the general rules for pleading. Rule 8(a)(2) requires a
24 "short and plain statement of the claim showing that the pleader is entitled to relief." The
25 current standard for a well pled complaint was set forth by the United States Supreme
26 Court in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and in *Ashcroft v. Iqbal*,
27 556 U.S. 662 (2009). "Factual allegations must be enough to raise a right to relief above
28 the speculative level on the assumption that all of the complaint's allegations are true. ...

1 Asking for plausible grounds does not impose a probability requirement at the pleading
 2 stage. It simply calls for enough fact to raise a reasonable expectation that discovery will
 3 reveal evidence of illegal agreement." (*Twombly* at 545.) The Court continued, "the
 4 Court is not requiring heightened fact pleading of specifics, but only enough facts to state
 5 a claim to relief that is plausible on its face."

6 Prior to the *Twombly/Iqbal* decisions, the Federal Rules of Civil Procedure
 7 allowed complaints for patent infringement to follow the format of Form 16 (Exhibit 1,
 8 attached hereto). All that was required was a one-sentence statement of patent ownership,
 9 a one-sentence perfunctory statement that the defendant is infringing, a one-sentence
 10 statement that the patent owner complied with patent marking requirements, and a one-
 11 sentence demand for relief. Form 16 no longer accompanies the Federal Rules, and its
 12 format is no longer acceptable for a well-pled complaint.

13 Fed. R. Civ. P. 8(b) lays out the rules for answering a complaint. Here, a
 14 defendant puts forth its denials and defenses. However, a counter-complaint requires
 15 more, *i.e.*, adherence to the rules set forth by *Twombly* and *Iqbal*. Enough facts must be
 16 pled so that a counterclaim defendant can put forth its defenses in response. Here, a
 17 counterclaim differs from an affirmative defense. The counterclaim plaintiff must show
 18 "that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

19 Trutek's complaint laid out sufficient detailed facts to show that BlueWillow's
 20 NanoBio[®] Protect product (NANOBIO) infringes at least claims 1, 2, and 7 of the '802
 21 Patent if those facts are taken as true. The complaint was specific enough to permit
 22 BlueWillow to respond to the substance of Trutek's allegations and to present affirmative
 23 defenses. However, BlueWillow's counter-complaint fails to present sufficient facts to
 24 permit Trutek to understand or to respond to BlueWillow's allegations.

25 //

26 **BlueWillow did not adequately plead its first counterclaim demanding a declaratory**
 27 **judgment of non-infringement according to the requirements of *Twombly* and *Iqbal*.**

28 On Page 6 of its Opposition, BlueWillow asserts, "[a]s an initial matter, it is not

1 necessary that a counterclaim explain 'why it does not infringe as that is a legal theory —
2 which is not required to be pled.'" However, the U.S. Supreme Court considered two
3 issues in patent litigation, claim construction and infringement. It held, "the first issue in a
4 patent case, construing the patent, is a question of law, to be determined by the court. The
5 second issue, whether infringement occurred, is a question of fact for the jury." *Markman*
6 *v. Westview Instruments*, 517 U.S. 370 (1996). Thus, contrary to BlueWillow's assertions,
7 in order to comply with the requirements of *Twombly* and *Iqbal*, BlueWillow must present
8 enough facts to show that it is entitled to a declaratory judgment of non-infringement.
9 Merely stating that it is not infringing is the equivalent of arguing the inverse of Form 16.
10 Such a statement is sufficient for a denial or an affirmative defense, but not for a
11 counterclaim contained in a counter-complaint.

12 Alternatively, on Pages 5 and 6 of its Opposition, BlueWillow alleges that it
13 "adequately pled factual matter sufficient to plead a counterclaim for non-infringement."
14 In Paragraph 13 of its Counter-Complaint (Document ECF 9, Pg. 21), BlueWillow
15 attempted to support its allegation of non-infringement with an example. Exhibit 2
16 (attached hereto) is a table comparing that example with the two independent claims of the
17 '802 Patent. BlueWillow is quoted in the right column next to each of the infringed
18 claims. It is evident that BlueWillow's example does not address the elements of either
19 independent claim, 1 or 2. Neither claim of the '802 Patent recites restriction of the flow
20 of airborne contaminants or particulate matter into the nasal passages, nor does it recite
21 holding airborne contaminants or particulate matter outside the body. This condition is
22 not an element of either independent patent claim 1 or 2.

23 However, it is evident that the claims of the '802 Patent recite electrostatically
24 attracting harmful particulate matter and inactivating the particulate matter by adding at least
25 one ingredient that would render said particulate matter harmless.

26 Exhibit 3 (attached hereto) is a reproduction of pages from BlueWillow's website
27 (<https://www.bluewillow.com>). On the second page of the exhibit, it states, "[t]he nano-
28 droplets are attracted to germs by electro-kinetic charge and present the BZK in such a

1 way to enable killing of germs on contact." (BZK is BlueWillow's abbreviation of
 2 benzalkonium chloride. *See* claim 7 in Exhibit 2). Thus, the admissions contained in
 3 BlueWillow's website directly contradict BlueWillow's assertions in its Answer to the
 4 Complaint and in its Opposition.

5 In the footnote on Page 7 of its Opposition, BlueWillow correctly stated that "[t]he
 6 burden of proof is on the patent owner, even in an action for declaratory judgment."
 7 *Pfizer, Inc. v. Apotex, Inc.*, 726 F.Supp.2d 921, 937 (N.D. Ill., 2010). However, at the
 8 complaint stage, the Court is not dealing with evidentiary proof. To overcome a motion to
 9 dismiss, the facts presented by the complainant are presumed true. *Iqbal* at 679.
 10 Nonetheless, in *Johnson v. City of Shelby*, 274 U.S. 10, 12 (2014), when commenting on
 11 *Twombly* and *Iqbal*, the Supreme Court held, "[a] plaintiff, they instruct, must plead facts
 12 sufficient to show that her claim has substantive plausibility."

13 However, the admissions by BlueWillow on its own website contradict the facts
 14 presented in its counter-complaint. Based on those admissions, BlueWillow's factual
 15 allegations in its counter-complaint are implausible and cannot possibly be accepted as
 16 true. The required support for a declaratory judgment of non-infringement was not
 17 asserted by BlueWillow.

18 //

19 **BlueWillow did not adequately plead its second counterclaim demanding a**
 20 **declaratory judgment of patent invalidity according to the requirements of *Twombly***
 21 **and *Iqbal*.**

22 On Page 11 of BlueWillow's Opposition, it states that, "BlueWillow adequately
 23 pled factual matter sufficient to plead a counterclaim for invalidity of the '802 Patent. In
 24 its Second Count, BlueWillow stated (§ 19) '[a]ll claims of the '802 Patent are invalid for
 25 failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and
 26 112.'" This is a statement of law – not of fact.

27 Legal issues are determined by application of facts to the law. Without the facts,
 28 there is no issue. "Issues averted to in a perfunctory manner, unaccompanied by some

1 effort at developed argumentation are deemed waived. It is not sufficient for a party to
2 mention a possible argument in the most skeletal way, leaving the court to put flesh on its
3 bones." *McPherson v. Kelsey*, 125 F.3d 989, 995-996 (6th Cir. 1997).

4 35 U.S.C. § 101 defines what inventions are patentable. It requires that inventions
5 must be novel and useful. 35 U.S.C. §§ 102 and 103 recite the standards for novelty. 35
6 U.S.C. § 112 recites the requirements for a properly submitted patent application.

7 When an application is examined by the United States Patent and Trademark
8 Office ("USPTO"), determinations by a patent examiner are findings of fact. There was
9 never a challenge to the usefulness of the invention of the '802 Patent at the USPTO.

10 In determining whether to allow Trutek's patent application to issue as the '802
11 Patent, the examiner made a thorough evaluation of its compliance with the requirements
12 of 35 U.S.C. §112. The USPTO prosecution history shows factually that while there were
13 initial rejections, the inventor was able to overcome them to bring the specification and
14 claims into full compliance.

15 The issue remaining is one of novelty. 35 U.S.C. § 102 establishes that an
16 applicant is not entitled to a patent if one or more claims of its application is anticipated
17 by the prior art (*i.e.*, someone else previously invented the exact same claimed invention).
18 Anticipation is a question of law based on underlying findings of fact.

19 35 U.S.C. §103 establishes that an applicant is not entitled to a patent if one or
20 more claims of its application is obvious over the prior art. "A patent claim is invalid as
21 obvious 'if the differences between the subject matter sought to be patented and the prior
22 art are such that the subject matter as a whole would have been obvious at the time the
23 invention was made to a [person having ordinary skill in the art].' Obviousness is a
24 question of law based on underlying facts." *Uniloc 2017 v. Apple, Inc.*, 843 Fed.Appx.
25 305, 312 (Fed. Cir. 2021).¹

26 To determine whether an invention is novel, patent examiners perform searches of

27 ¹ Emphasis added. Further the acronym PHOSITA means, "person having ordinary skill
28 in the art."

1 the prior art. If a search yields one or more prior publications (patent or otherwise) that
2 renders a claim as either anticipated or obvious, the claim is rejected. The rejection may
3 be overcome by the applicant either through successful argument or by amendment to
4 overcome the limitations of the prior art.

5 Unfortunately, prior art searches, performed either by applicants or USPTO
6 examiners, are rarely complete. In a subsequent action, either in court or at the USPTO,
7 claims of an issued patent may be shown to be invalid if prior art is discovered that was
8 not considered by the examiner during the prosecution history.

9 On Page 11 of its Opposition, BlueWillow alleged that six prior art references
10 render each claim of the '802 Patent either anticipated (under 35 U.S.C. § 102) or obvious
11 (under 35 U.S.C. § 103). The prosecution history of the '802 Patent shows that one of the
12 alleged references was previously considered by the examiner when he decided to allow
13 the application to issue as a patent. Regarding the remaining prior art references, the mere
14 patent or publication numbers do not constitute facts. BlueWillow stated, "[f]or example,
15 at least the following prior art references render each claim of the '802 Patent invalid
16 under 35 U.S.C. § 102 and/or § 103." Here, rather than alleging facts, BlueWillow is
17 asserting a mere possibility. Which claim(s) is invalid and under which statute? Further,
18 if any one claim of a patent is valid and infringed, the entire patent is infringed. Without
19 more, BlueWillow is requiring Trutek to make an uninformed denial without any factual
20 basis for evaluation.

21 A counterclaim requesting a declaratory judgment of patent invalidity is different
22 from an affirmative defense of patent invalidity. With an affirmative defense, a defendant
23 is entitled to develop its defense through discovery. However, a counterclaim is an
24 integral part of a counter-complaint, which as a complaint, must meet the requirements set
25 forth by the Supreme Court in *Twombly* and *Iqbal*. At least some specific facts must be
26 alleged, which if plausible, entitle the counter-plaintiff relief in the form of a declaratory
27 judgment.

28 On Page 12 of its Opposition, BlueWillow stated, "[i]ndeed, a patent is invalid

1 unless it satisfies every statutory requirement for patentability.” BlueWillow is required
2 to plead facts that, if presumed true, would render the patent invalid under one or more of
3 these alleged provisions. However, BlueWillow actually pled no such facts. On Page 13,
4 BlueWillow stated that, “[i]t is not necessary at the pleading stage to describe in detail
5 every potential ground for invalidity.” Nevertheless, BlueWillow presented no facts to
6 establish patent claim invalidity.

7 “If a pleading fails to specify the allegations in a manner that provides sufficient
8 notice, a defendant can move for a more definite statement under Rule 12(e) before
9 responding.” *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 513 (2002). “The Court has the
10 power to dismiss a complaint *sua sponte* pursuant to Rule 12(b)(6), provided that the
11 plaintiffs have been given adequate notice and an opportunity to amend.” *O’Lear v.*
12 *Miller*, 222 F.Supp.2d 862, 863 (E.D. Mich. 2002).

13 //

14 **PRAYER FOR RELIEF**

15 Trutek hereby repeats its request that BlueWillow's Counter-Complaint along with
16 its two counterclaims be dismissed under Fed. R. Civ. P. 12(b)(6) for failure to state a
17 claim showing that it is entitled to relief.

18
19 Dated: July 23, 2021

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CERTIFICATE OF ELECTRONIC SERVICE

I hereby certify that on July 23, 2021, I electronically filed this document, **PLAINTIFF/COUNTER-DEFENDANT TRUTEK CORP.'S REPLY TO DEFENDANT-COUNTER PLAINTIFF BLUEWILLOW BIOLOGICS, INC.'S OPPOSITION TO PLAINTIFF'S MOTION TO DISMISS DEFENDANT'S COUNTERCLAIMS**, with the Clerk of the Court for the Eastern District of Michigan using the ECF System.

s/ Stanley H. Kremen
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